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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/693,043

10/20/2000

Anders Bjorklund

17810-513 (SCI-13)

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7590

08/09/2006

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EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,043

Applicant(s)

BJORKLUND, ANDERS

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,13 and 14 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3,6,13 and 14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 20 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

The amendment filed May 2, 2006 (hereinafter referred to as "the response") has been entered. Claim 1 has been amended.

Accordingly, Claims 1-3, 6, 13, and 14 remain pending in the instant application.

The rejection of Claims 1-3, 6, 13, and 14 under 35 U.S.C. 112, first paragraph, for containing new matter, is withdrawn in view of the amendment to Claim 1 which removes the new matter from the claims.

The rejection of Claims 1-3, 6, 13, and 14 under 35 U.S.C. 112, second paragraph, for indefiniteness, is withdrawn in view of the amendment to Claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-3, 6, 13, and 14 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 5-8 of the Office Action mailed 11/17/05, on pages 3-5 of the Office Action mailed 2/23/05, on pages 3-7 of the Office Action mailed 6/3/04, on pages 2-9 of the Office Action mailed 5/12/03, on pages 2-5 of the Office Action mailed 7/16/02, and for further reasons as discussed herein, as containing subject matter which was not described in the specification in such a way as to

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enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At pages 5-7 of the response, Applicants assert that their specification and the evidence of record demonstrates that the ordinarily skilled artisan could discern an appropriate method of use without undue experimentation. Applicants point to the specification teachings relating to how to transplant CNS neural stem cells and induce migration. Applicants further assert that the graft survival and reinnervation shown in the specification are indicative of a therapeutic effect. However, the art cited in this case, particularly Milward et al. demonstrate that even when grafted cells integrate normally, the clinical deficit of the animals is not ameliorated. Given the unpredictability in the art of therapeutic transplantation, the development of therapeutic protocols requires substantial experimentation. In view of the limited guidance, this substantial experimentation rises to the level of undue experimentation.

At pages 5-7 of the response, Applicant asserts that the evidence of record confirms that transplantation of neural stem cells can be routinely achieved. Applicant further asserts that such transplantation results in a therapeutic benefit to the host. No support is offered for this assertion. While non-therapeutic transplantation can be performed (i.e. cells may be implanted into the brain by a practitioner), protocols within the scope of the instantly claimed invention that produce a therapeutic effect were not available at the time of the invention, and given the state of the art, for reasons of record, undue experimentation would have been required to develop protocols within the scope of the claims that produce a therapeutic effect in a diseased animal.

At pages 5-7 of the response, Applicant asserts that the claimed method of transplantation would be useful as a restorative therapy for neurodegenerative diseases. Applicant further asserts that the evidence of record demonstrates that the improvement of delivering a mitogenic growth factor according to the claimed methods would also provide a therapeutic benefit to the host. No support is offered for these assertions, except to point broadly to the evidence of record. However, the evidence of record has

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already been addressed in detail in the prior Office Actions, particularly at pages 5-9 of the Office Action of 5/12/03 and pages 6-7 of the Office Action of 6/3/04.

At page 7 of the response, Applicants assert that they do not believe that the law requires the demonstration of a therapeutic benefit. However, the only utility asserted in the specification for the claimed method is to produce a therapeutic effect. Thus, the specification must provide adequate guidance to enable one of skill in the art to achieve the asserted utility. The specification asserts no utility for non-therapeutic transplantation. Applicants cite the decision of the Board of Patent Appeals and Interferences in Appeal No. 2005-2594. However, in that case, the Board accepted that a treatment effect could be rendered by the claimed method based on the prophetic examples of the specification, which the Board understood to be actual working examples.

Given the unpredictability in the art of therapeutic transplantation, the development of therapeutic protocols requires substantial experimentation. In view of the limited guidance, this substantial experimentation rises to the level of undue experimentation.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER